IPM 005B

A PHASE I/II SINGLE-CENTRE DOUBLE-BLINDED, RANDOMIZED STUDY OF THE SAFETY AND TOLERABILITY OF DAPIVIRINE VAGINAL MICROBICIDE GEL (TMC 120 GEL-002) VS. HEC-BASED UNIVERSAL PLACEBO GEL IN HEALTHY HIV-NEGATIVE WOMEN

SPONSOR:

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PROTOCOL SYNOPSIS

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DESIGN:	This study is a double blinded, randomized, two-arm, single-site trial in Belgium to assess the local safety on vulval and cervicovaginal mucosa, systemic toxicity, and tolerability of twice daily use of Dapivirine Gel-002 in healthy HIV-negative women for 42 days. **Participant**s will be randomized to receive either 0.02% (200 µg/mL) Dapivirine Gel-002 or an HEC-based universal placebo gel. All **participant**s will receive condoms. Acceptability and compliance with the use of the gel will be assessed. **Participant**s will be monitored on Days 7, 28 and 42 for safety, tolerability and compliance.
STUDY POPULATION:	Healthy, HIV-negative women aged ≥18 and ≤ 50 living in Belgium with no clinically detectable genital abnormality (including vulval, vaginal, cervical, and/or perineal ulcer and/or lesion), no abnormal or grossly bloody Pap smear, nor internal vaginal warts.
SAMPLE SIZE:	**Approximately** 36 **participant**s will be enrolled.
REGIMEN:	At entry, **participant**s will be randomized 2:1 to one of the following study arms for 42 days of treatment: Arm A: 0.02% Dapivirine Gel-002 (67 % of **participant**s) Arm B: HEC-based placebo gel (33 % of **participant**s) Randomization will be double blinded. **Participant**s will self-apply 2.5 mL of study gel with pre-filled applicators b.i.d. (shortly after awakening and in the evening approximately 12 hours after morning application). The first gel application will be applied by the **participant** at the site under the supervision of a clinical staff member (direct observation is optional). **Participant**s will remain in the clinic under observation for 30 minutes after the first application. Application of the study gel will continue twice daily, regardless of sexual activity, for 42 days including during menses. However, failure to apply the gel during menses will not result in a protocol violation. **Participant**s will be instructed not to use the gel rectally. All **participant**s will be given condoms.

Treatment for urinary and genital infections (except HPV) will be provided from screening **through** Day 56.

STUDY DURATION: It is anticipated that the study will be accrued in approximately 3-4 months. **Participant**s' total participation will be **28 days in screening and** 56 days **of follow-up**.

PRIMARY OBJECTIVES:

- To assess the local safety and tolerability on vulval and cervicovaginal mucosa of Dapivirine Gel-002 when applied twice daily for 42 days at a concentration of 0.02% compared to an HEC-based "universal" placebo.

- To assess the systemic safety of Dapivirine Gel-002 when applied twice daily for 42 days at a concentration of 0.02% compared to an HEC-based "universal" placebo

SECONDARY OBJECTIVES:

- To assess the acceptability of Dapivirine Gel-002 when applied twice daily for 42 days at a concentration of 0.02% compared to an HEC-based "universal" placebo.

- To assess compliance to Dapivirine Gel-002 when applied twice daily for 42 days at a concentration of 0.02% compared to an HEC-based "universal" placebo in HIV-negative women.